IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	
Plaintiff,	)	
v.	)	**Case No. 3:05-0444**
	)	**Judge Trauger**
PFIZER INC., *et al.*,	)	
Defendants.	)	

MEMORANDUM

Among the numerous motions *in limine* pending before the court are five motions *in limine* filed by the defendants (Docket Nos. 101, 104, 109, 121, and 124). These motions have been fully briefed, and the court's findings are discussed below.

BACKGROUND

On May 13, 2004, 79-year-old Richard Smith ("Smith") committed suicide. Two months earlier, Smith had filled a prescription for the medication Neurontin, which is manufactured by defendants Pfizer Inc. and Warner-Lambert Co. LLC (collectively, "Pfizer" or "defendants"). Smith's doctor prescribed Neurontin to treat his neuropathic pain, which is an off-label use of the drug. Smith's widow, plaintiff Ruth Smith, alleges that Smith's ingestion of Neurontin caused his suicide. The plaintiff also alleges that, since the early 1990s, the defendants have aggressively marketed Neurontin for off-label use.

Further background can be found in the court's recently filed Memorandum addressing

several other motions *in limine* filed by the parties. (Docket No. 191 at 2-3.)

ANALYSIS

The parties have filed numerous motions *in limine*. This Memorandum will address five of these motions.

I. The Defendants' Motion to Exclude Evidence of and References to Warner-Lambert Co. LLC's Guilty Plea or any Related Government Investigations or Agreements (Docket No. 124)

The defendants argue that the court should exclude any reference to the fact that Warner-Lambert Co. LLC pleaded guilty to certain instances of marketing Neurontin for off-label uses. This motion will be denied.

In May 2004, Warner-Lambert pleaded guilty to felony counts of illegally promoting Neurontin for off-label use and illegally failing to label Neurontin with directions for such off-label use. In its guilty plea, Warner-Lambert admitted the truth of the facts set forth in the criminal Information that was attached to the plea. (Docket No. 183, Ex. 2 at 1.) The Information listed specific examples of Warner-Lambert's efforts to market the drug in 1995 and 1996, including its promotion of Neurontin for pain treatment at a consultant meeting, (Docket No. 126, Ex. 1 ¶¶ 25-26), and its promotion of off-label use during a series of teleconferences with doctors. (*Id.* ¶¶ 33-35.)

The defendants argue that the guilty plea is irrelevant to the plaintiff's claims. But the plea – or, more specifically, Warner-Lambert's admission of the facts listed in the Information[1] –

[1] The defendants claim that, although the plea itself is admissible as a party admission, the Information is inadmissible as hearsay. (Docket No. 125 at 4 n.5.) This is incorrect, because the plea attaches the Information and incorporates it by reference. Moreover, the plea

is highly relevant for the same reasons that other evidence of the defendants' marketing campaigns is relevant. (*See* Docket No 191 at 12-14.) This is particularly true because, as the defendants themselves highlight, "Warner-Lambert denied, and Pfizer continues to deny, the existence of any intentional nationwide scheme to promote Neurontin for off-label use." (Docket No. 125 at 3.) The plea serves as an admission that Warner-Lambert engaged in the off-label marketing activity outlined in the Information.

Additionally, the admission of the guilty plea will not unduly prejudice the defendants. The probative nature of the evidence outweighs any prejudice that the defendants might experience. *See United States v. Haddix*, No. 5:07-137, 2008 U.S. Dist. LEXIS 2019, at *6 (E.D. Ky. Jan. 9, 2008) ("The Court finds that [evidence of the defendant's guilty plea] is not, per se, so prejudicial as to outweigh the probative value of the evidence under Fed. R. Evid. 403. Assuming that evidence of the drug transactions is offered, it follows that the United States should be allowed to offer evidence of Haddix's admission that he, in fact, participated in the transactions."). Nor is the guilty plea barred under Rule 404(b), for the same reasons that the rule does not bar other evidence of the defendants' marketing. (*See* Docket No. 191 at 14-15.)

The defendants argue that allowing the jury to impose punitive damages based on the conduct that led to the guilty plea would violate the their due process rights. (Docket No. 125 at 7-11.) In support of this argument, they primarily cite *Phillip Morris USA v. Williams*, 549 U.S.

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specifically provided that Warner-Lambert admitted "that the facts set forth in the Information are true." (Docket No. 183, Ex. 2 at 1.) The court does agree that other related documents, such as the government's press releases or the government's Sentencing Memorandum, are inadmissible hearsay.

346 (2007), and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003).

In *Phillip Morris*, the Court held that punitive damages may only be assessed for conduct that harmed the plaintiff, as opposed to conduct that harmed nonparties to the litigation:.

> Evidence of actual harm to nonparties can help to show that the conduct that harmed the plaintiff also posed a substantial risk of harm to the general public, and so was particularly reprehensible – although counsel may argue in a particular case that conduct resulting in no harm to others nonetheless posed a grave risk to the public, or the converse. Yet for the reasons given above, a jury may not go further than this and use a punitive damages verdict to punish a defendant directly on account of harms it is alleged to have visited on nonparties.

549 U.S. at 355.

Similarly, the Court held in *Campbell* that "[a] defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages. A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business." 538 U.S. at 422-23. *Campbell* also addressed federalism, as it relates to punitive damages: "Lawful out-of-state conduct may be probative when it demonstrates the deliberateness and culpability of the defendant's action in the State where it is tortious, but that conduct must have a nexus to the specific harm suffered by the plaintiff." *Id.* at 422.

Here, evidence of a national marketing scheme to promote Neurontin's off-label benefits is not "independent from the acts upon which" the plaintiff seeks to impose liability. As described above, any such scheme bears directly on the plaintiff's negligence claim, because it

affects the defendants' duty to test the safety of their drug for off-label uses and label it accordingly. Furthermore, the federalism concerns discussed in *Campbell* are not present here; for the same reasons that a national marketing scheme is relevant to Smith's negligence claim, it has a "specific nexus" to the harm alleged by the plaintiff.

Accordingly, the defendants' motion will be denied.

II. The Defendants' Motion to Exclude Evidence of Post-Incident Regulatory Actions, Labeling, and Patient Information Guides (Docket No. 101)

The defendants argue that the court should exclude evidence of the FDA's April 2009 action regarding Neurontin labeling, as well as new versions of the warning label and patient guide that the defendants currently include with the drug. This motion will be denied.

In 2008, the FDA conducted a meta-analysis of studies on anti-epileptic drugs, including Neurontin, and concluded that these drugs might increase patients' risk of committing suicide. As a result of this study, in 2009, the FDA required the manufacturers to add warning labels stating that the drugs might increase the risk of suicidal behavior and ideation. Pfizer complied by adding these warnings to its Neurontin labeling and Neurontin patient guide.

The defendants claim that evidence of these actions is irrelevant. (Docket No. 102 at 2-3.) It is true that the MDL court found that "the decision by the FDA to require warnings on a drug label, without more, does not suffice to establish causation." *In re Neurontin Mktg.*, 612 F. Supp. 2d 116, 137 (D. Mass. 2009). This is because, "when evaluating pharmaceutical drugs, the FDA often uses a different standard than a court does to evaluate evidence of causation in a products liability action." *Id.* The FDA typically "err[s] on the side of caution." *Id.* (citation omitted). But the fact that this evidence is not *sufficient* to establish causation does not mean

that it is not *relevant* to the issue of causation.

Indeed, the FDA's actions tend to show that the agency believes that Neurontin can cause suicide-related side effects. The evidence is probative because it reflects the FDA's views on causation. "Moreover, the new guides indicate that there were studies and pharmacovigilance that Defendants could have performed to issue the appropriate warnings." (Docket No. 151 at 12.) Thus, the evidence is relevant.

The defendants express concern that the jury will "be misled to believe that Neurontin's subsequent labeling changes constitute an admission by Defendants that the prior label was inadequate." (Docket No. 122 at 4.) But this seems unlikely. The defendants can certainly inform the jury that the changes to the label were required by the FDA, were not voluntarily undertaken by Pfizer, and did not constitute an admission by Pfizer that the risk of suicide-related side effects actually exists. *Cf. Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 94 (2d Cir. 1980) (finding error when the court instructed the jury that subsequent product labeling, mandated by the FDA, "could be considered as admissions by [the defendant]").

Finally, the defendants argue that the new label and patient guide are inadmissible under Federal Rule of Evidence 407, which states that "subsequent measures" that "would have made the [previous] injury or harm less likely to occur" are inadmissible "to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction." Fed. R. Evid. 407. The general policy behind the rule is to encourage defendants to take proper remedial actions, without worrying that such actions will be used against them in court. 2 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence*, § 407.03[1]

(2d ed.); *see also Polec v. Northwest Airlines (In re Air Crash Disaster)*, 86 F.3d 498, 529 (6th Cir. 1996). Courts generally find that Rule 407 applies when a defendant *voluntarily* takes remedial measures. *In re Air Crash Disaster*, 86 F.3d at 529. But "where a superior authority requires a tort feasor to make post-accident repairs, the policy of encouraging voluntary repairs which underlies Rule 407 has no force – a tort feasor can not be discouraged from voluntarily making repairs if he must make repairs in any case." *Kociemba v. G. D. Searle & Co.*, 683 F. Supp. 1579, 1581 (D. Minn. 1988) (quoting *Herndon v. Seven Bar Flying Serv., Inc.*, 716 F.2d 1322, 1331 (10th Cir. 1983)).

Here, the FDA mandated that Pfizer add the warnings. The policy behind Rule 407 is not implicated, so it does not bar admission of the 2009 label and patient guide. *Rozier v. Ford Motor Co.*, 573 F.2d 1332, 1343 (5th Cir. 1978) (declining to apply Rule 407 because "the remedial measure was to be required in any event by a superior authority, the National Highway Traffic Safety Administration"); *Lolie v. Ohio Brass Co.*, 502 F.2d 741, 744 (7th Cir. 1974) (admitting evidence that a state mine inspector ordered a mine operator to add support to a power cable after an accident). Because evidence of the FDA's regulatory actions and the 2009 label and patient guide are relevant and not otherwise barred, the defendants' motion will be denied.

III. The Defendants' Motion to Exclude the Testimony of David Franklin and Evidence of the *Franklin* litigation (Docket No. 121)

The defendants argue that the court should exclude the testimony of Dr. David Franklin and evidence of the *qui tam* action *United States ex rel. Franklin v. Parke-Davis, et al.* The motion will be granted in part and denied in part.

Franklin was employed by the defendants for four months in 1996 as a medical liaison in

Massachusetts. He allegedly received sales training that instructed him to market Neurontin to doctors for off-label purposes. Franklin subsequently filed a *qui tam* action alleging that the defendants had been improperly reimbursed by Medicaid for off-label Neurontin prescriptions. The plaintiffs plan to have Franklin testify at trial.[2]

Much of the defendants' brief relates to the general admissibility of information regarding their alleged nationwide off-label marketing efforts. The court has already determined that such information is relevant and admissible. (*See* Docket No. 191 at 12-15.) To the extent that Franklin's testimony relates to a national marketing campaign, his testimony is similarly relevant and admissible.

The defendants highlight the Disclosure of Information drafted by Franklin and attached to the complaint in the *Franklin* case. This Disclosure contains Franklin's transcriptions of statements by his superiors directing medical liaisons to sell Neurontin for off-label purposes. (*See* Docket No. 123, Ex. 3 at 10-11.) The defendants claim that this is double hearsay and is thus inadmissible. (Docket No. 122 at 8-9.) Although the Disclosure itself is hearsay, the statements made by the defendants' employees are non-hearsay because they count as admissions by the defendants. *See* Fed. R. Evid. 801(d)(2)(D). Accordingly, Franklin may testify at trial regarding the statements. The defendants argue that Franklin may not use the Disclosure at trial to refresh his recollection. (Docket No. 122 at 11.) But trial is the proper time

[2] The defendants point out that Franklin may not offer expert testimony (Docket No. 122 at 4-6), but the plaintiff maintains that Franklin will testify as to his "personal knowledge on the way that [the defendants' marketing] programs worked." (Docket No. 166 at 13.) If Franklin testifies outside his personal knowledge, offers speculative testimony, or testifies regarding Pfizer's motives or intent, the defendants can object at trial.

for the court to address the propriety of using the document to refresh Franklin's recollection of events.

The defendants also argue that depositions from the *Franklin* action are inadmissible hearsay. If a witness is unavailable, testimony from his or her previous deposition falls under the hearsay exception of Rule 804(b)(1) if the "the party against whom the testimony is now offered . . . had an opportunity and similar motive to develop the testimony by direct, cross, or redirect examination." Fed. R. Evid. 804(b)(1). The defendants claim that "[t]he only question in the *qui tam* action was whether Warner-Lambert promoted Neurontin off-label and whether such off-label promotion caused the submission to Medicaid of Neurontin prescriptions that were ineligible for reimbursement." (Docket No. 122 at 10.) "Consequently, Warner-Lambert's motive in cross examining the Franklin witnesses was merely to demonstrate that it did not encourage off-label promotion of Neurontin." (*Id.*) But this is exactly the same motive the defendants have today; it is not, as the defendants claim, "wholly irrelevant to the instant case." (*Id.* at 10-11.) The *Franklin* evidence is relevant precisely because it shows that the defendants encouraged off-label marketing. The defendants' motive in 1996 to deny a nationwide off-label marketing scheme was just as strong as their motive today.

The court agrees with the defendant, however, that deposition testimony from the Franklin case is inadmissible to the extent that it relates to "the safety and efficacy of Neurontin." (Docket No. 122 at 11.) It seems possible that the plaintiff will offer deposition evidence for this purpose; she claims that evidence from the *Franklin* litigation will "demonstrate that Defendants were on notice . . . of the risks of depression, adverse mood and

behavior changes and the increased risk for suicide." (Docket No. 166 at 4.) The defendants did not have a similar motive to develop testimony on this point during the *Franklin* litigation as they do today.

Accordingly, the defendants' motion will be granted in part and denied in part. Depositions from the *Franklin* action are inadmissible to the extent they relate to the safety and efficacy of Neurontin. As described and limited above, other evidence from the case is admissible.

IV. The Defendants' Motion to Exclude Evidence of Anecdotal Adverse Event Reports (Docket No. 109)

The defendants argue that the court should prevent the plaintiff from introducing anecdotal examples of adverse event reports related to Neurontin. This motion will be granted.

Federal regulations require pharmaceutical companies to track "adverse drug experiences" suffered by patients and relay them to the FDA. 21 C.F.R. § 341.80. The FDA then catalogs these adverse event reports. The reports, however, have "inherent biases as they are second-or-third hand reports, are affected by medical or mass media attention, and are subject to other distortions." *DeLuca v. Merrell Dow Pharm., Inc.*, 791 F. Supp. 1042, 1050 (D.N.J. 1992). The plaintiffs argue that the reports are relevant because they provided notice to the defendants of possible problems with Neurontin. (Docket No. 159 at 3-4.) They also argue that the reports can show a causal relationship between Neurontin and suicide. (*Id.* at 5.)

The court agrees with the defendant that the plaintiff should not be allowed to introduce numerous individual adverse event reports. Although the plaintiff is correct that adverse event reports are probative of notice, this is only true when they are viewed in the aggregate. In the

context of a drug that is prescribed to millions of people, any single suicide does not give the manufacturer notice that the drug might have dangerous side effects. Thus, isolated, anecdotal adverse event reports, are not probative of the notice that the defendants received. *See* Fed. R. Evid. 402 (stating that irrelevant evidence is inadmissible).

The plaintiff's experts will testify as to whether the total number of suicide-related adverse event reports should have placed the defendants on notice regarding Neurontin's alleged side effects. This will allow the plaintiffs to sufficiently explore the trends in the reports.

Accordingly, the defendant's motion will be granted. The court will, however, allow the plaintiff to introduce one adverse event report in conjunction with the testimony of her experts, to illustrate the format of the document for the jury.

V. The Defendants' Motion to Exclude Evidence of Loss of Consortium Damages Suffered by the Decedent's Children (Docket No. 104)

The defendants argue that evidence of the loss of consortium damages suffered by Smith's children is irrelevant and inadmissible under Tennessee law. This motion will be denied.

Tennessee law provides that "[a] suit for the wrongful killing of the spouse may be brought in the name of the surviving spouse for the benefit of the surviving spouse and the children of the deceased, in the name of the administrator of the deceased spouse or in the name of the next of kin of the spouse." Tenn. Code. Ann. 20-5-110(a). In *Jordan v. Baptist Three Rivers Hospital*, 984 S.W.2d 593 (Tenn. 1999), the Tennessee Supreme Court unambiguously held:

> [C]onsortium-type damages may be considered when calculating

> the pecuniary value of a deceased's life. This holding does not create a new cause of action but merely refines the term "pecuniary value." Consortium losses are not to limited to spousal claims but also necessarily encompass a child's loss, whether minor or adult.

984 S.W.2d at 601.

Nevertheless, the defendants, after explaining the history of Tennessee's wrongful death statutes, argue that section 20-5-110(a) is a "vestigial section of the Code" that has been repeatedly read out of context by the Tennessee Supreme Court. (Docket No. 105 at 5, 7.) According to the defendants, Tennessee's wrongful death statute does not allow a decedent's adult children to recover loss of consortium damages if the decedent's spouse has brought the action. They claim that federal courts, including the Sixth Circuit, have "felt constrained by the[] incorrect holdings" of Tennessee state courts. (*Id.* at 9.)

This court remains so constrained. Indeed, this court has previously recognized that "the Tennessee courts have consistently allowed for [adult children's loss of consortium] damages when a wife has brought a wrongful death action on behalf of herself and the estate of her spouse." *Matheny v. Tenn. Valley Auth.*, 523 F. Supp. 2d 697, 729 (M.D. Tenn. 2007) (citing *Jordan*, 984 S.W.2d at 601; *Hunter v. Ura*, 163 S.W.3d 686, 705 (Tenn. 2005)), *rev'd on other grounds by* 557 F.3d 311 (6th Cir. 2009). Although the Sixth Circuit reversed *Matheny* on other grounds, it noted that "Tennessee's wrongful death statute . . . allows for recovery of the pecuniary value of the decedent's life, which includes . . . the value of intangible consortium losses sustained by a decedent's spouse *and children*." 557 F.3d at 320 (emphasis added); *see also Coggins v. KILLM, Inc.*, 146 Fed. Appx. 9, 12 (6th Cir. 2005).

This court is bound to follow the Tennessee Supreme Court's, and the Sixth Circuit's,

interpretation of Tennessee's wrongful death statutes. Because parental loss of consortium damages are allowed, evidence of such damages is relevant and admissible. Accordingly, the defendants' motion will be denied.

CONCLUSION

For all of the reasons discussed above, the court will grant the defendants' Motion to Exclude Evidence of Anecdotal Adverse Event Reports and grant in part the defendants' Motion to Exclude the Testimony of David Franklin and Evidence of the *Franklin* Litigation. The court will deny the remainder of the above-listed motions *in limine*.

An appropriate order will enter.

ALETA A. TRAUGER
United States District Judge